IN THE UNITED STATED DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE, AT KNOXVILLE

KELLY PAINTER-HART AND SETH HART, her husband,	)	
Plaintiffs,	)	
v.	)	**Civ. No.**
	)	**JURY DEMAND**
SIENTRA, INC.	)	
Defendant.	)	

COMPLAINT

Come now the Plaintiffs, by and through counsel, and for a cause of action against Defendant would state as follows:

Parties

1. Kelly Painter-Hart and her husband, Seth Hart ("Plaintiffs") are citizens and residents of the State of Tennessee.

2. Defendant Sientra, Inc., (hereinafter referred to as "Sientra") by information and belief, is and was at all times relevant to this Complaint a Delaware corporation with its principal place of business located at 420 South Fairview Avenue, Suite 200, Santa Barbara, California 93117. Defendant Sientra does business in and/or directs its activities in the State of Tennessee including, but not limited to, willfully advertising, selling and delivering the product at issue in Tennessee.

3. Defendant Sientra may be served with process through its registered agent for service of process: Corporation Service Company 251 Little Falls Drive, Wilmington, Delaware, 19808.

4. Defendant Sientra is a medical aesthetics company that develops and sells medical aesthetic products to plastic surgeons in the State of Tennessee. Sientra offers silicone gel breast

implants for use in breast augmentation and breast reconstruction procedures, as well as breast tissue expanders.

Jurisdiction and Venue

5. This court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the parties are citizens of different states and the amount in controversy exceeds $75,000, exclusive of interests and costs.

6. Venue is proper in the Eastern District of Tennessee, pursuant to 28 U.S.C. § 1391(a)(2), because Mrs. Hart's prophylactic double mastectomy and reconstruction utilizing the products of Defendant Sientra occurred within this district, as well as her resultant diagnosis with breast implant associated large cell anaplastic lymphoma and the subsequent treatment therefor.

Factual Allegations

A. Plaintiff Kelly Painter Hart's development of Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

7. Plaintiff Kelly Hart is a wife and mother who prioritized safety for herself and her family. Accordingly, on or about November 13, 2013, Mrs. Hart underwent prophylactic bilateral risk-reduction mastectomies. For reconstruction, Sientra textured oval shaped silicone gel 500/ 550 mL high-profile implants were utilized. (Product or catalog number: 20645-550HP; serial numbers 4459683 and 4470864).

8. At no time was Mrs. Hart informed of increased risk associated with textured implants, of the increased risks of using a product manufactured in Brazil, or of manufacturing and quality control issues that could impact her health, safety and well-being.

9. Mrs. Hart chose to undergo double mastectomies in order to avoid the risk of developing cancer. Had she been informed of any increased risk of developing cancer associated

with Sientra textured implants manufactured in Brazil, she would not have chosen to use that product and/or would have opted out of reconstruction.

10. Upon information and belief, her surgeon, Dr. Jay Lucas, was also not warned of increased risks associated with textured implants, of the increased risks of using a product manufactured in Brazil, or of manufacturing and quality control issues that could impact the health, safety and well-being of his patients.

11. On September 26, 2019, Mrs. Hart returned to Dr. Lucas in Knoxville, Tennessee, with complaints of acute swelling of her right breast. He ordered a diagnostic ultrasound with aspiration to evaluate the possibility of breast implant associated anaplastic large cell lymphoma (BIA-ALCL). This procedure was performed at Parkwest Medical Center in Knoxville, Tennessee.

12. On approximately October 1, 2019, Mrs. Hart was seen by oncologist Dr. Daniel Ibach who confirmed her that laboratory testing on the aspirated fluid revealed the presence of breast implant associated anaplastic large cell lymphoma (BIA-ALCL) in her right breast.

13. Mrs. Hart underwent surgery to remove the Sientra implants on or about November 11, 2019.

14. Mrs. Hart required and will continue to require follow up medical care, testing and monitoring related to her breast implant associated cancer.

15. Mrs. Hart's breast implant associated anaplastic large cell lymphoma (BIA-ALCL) was caused by textured Sientra breast implants that were defective, unreasonably dangerous, and/or adulterated, and were not manufactured in compliance with applicable laws, regulations and/or standards, all as addressed in more detail below.

B. Sientra Breast Implants

16. Breast implants are medical devices that are used to augment breast size, to reconstruct the breast following mastectomy, or to correct a congenital abnormality. Breast implants consist of a silicone outer shell and a filler, most commonly silicone gel or saline.[1] The outer shell can be smooth or textured, which purportedly provides greater friction between the implant and its surroundings, allowing it to remain in a more stable position.

17. The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration approved the premarket approval application (PMA) for Sientra breast implants on March 9, 2012. The approval allowed distribution of the device *in accord with the conditions of approval* outlined in the letter.

18. The conditions of approval referenced FDA requirements governing the manufacture, distribution, and marketing of devices, along with reporting requirements, including Annual Reports, post-approval study (PAS) reports, and adverse event reporting. The PAS reports included specific data requirements for a Cohorts study, a Continued Access study, a US post-approval study, Case-Control studies, and a Focus Group study.

19. The FDA similarly has requirements regarding contractor selection.

20. The approval letter further directed that "[f]ailure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law."

[1] FDA and Center for Devices and Radiological Health U.S. Food and Drug Administration Update on the Safety of Silicone Gel-Filled Breast Implants, June 2011 at p.3. ("2011 FDA Update on Breast Implant Safety"), https://www.fda.gov/media/80685/download.

21. The premarket application (PMA) process is generally confidential, and documents generated as part of that process are not subject to public disclosure. Accordingly, additional information is expected to be developed during discovery regarding the specific requirements applicable to Sientra, in addition to those referenced here. However, those cannot be plead with any greater specificity, as Plaintiffs do not yet have access to all relevant documents within the unique control of Defendant Sientra and the FDA.

22. In addition to the specific requirements outlined in the application and approval, Sientra was also subject to general requirements to comply with FDA regulations, current Good Manufacturing Processes (cGMP), the Quality System Regulations (QSRs), and requirements regarding contractor selection, testing and quality control measures.

23. Some of the applicable regulations to which Sientra was subject can be found in 21 C.F.R. §§ 803, 808, 814, and 820 (2012). Those regulations include, but are not limited to, regulations regarding audit procedures, production and process controls, labeling and packaging controls, and handling controls. This Complaint includes, but is not limited to, allegations of violations of these regulations, which are identified in more detail below, and which are specifically incorporated herein by reference.

24. Because Sientra advertised, sold, and/or delivered its product in the State of Tennessee, Sientra was also subject to parallel State regulation, including but not limited to the statutes and laws referenced in more detail below. These regulations, laws and/or statutes are and were equivalent to federal law, and imposed no different or additional duties on Sientra.[2]

25. According to Defendant Sientra's initial prospectus filed with the Securities and Exchange Commission[3] :

[2] To the extent this Court determines that any State provision is not parallel to federal requirements, that provision should be severed from other allegations, so that the parallel requirements may stand.

> "[W]e incorporate differentiated technologies into our breast implants, including a proprietary high-strength, cohesive silicone gel and proprietary texturing branded TRUE Texture… We do not have any patents or patent applications, but rely on trade secrets, proprietary know-how and regulatory barriers to protect our products and technologies."

26. At all times material to this action, the silicone breast implants sold by Defendant Sientra, in the United States and within the State of Tennessee, were made and/or manufactured by a privately-held Brazilian company called Silimed Industria de Implantes Ltda. ("Silimed"). *See* Section C, below, for additional information regarding Silimed.

27. Sientra stated in its 2014 annual report:

> "In addition, **our reliance on Silimed involves a number of other risks, including among other things that…our products may not be manufactured in accordance with agreed upon specifications or in compliance with regulatory requirements, or its manufacturing facilities may not be able to maintain compliance with regulatory requirements, which could negatively affect the safety or efficacy of our products** or cause delays in shipments of our products."

(Emphasis added).[4]

28. Subject to additional discovery, Sientra did not comply with the terms of the approval letter and/or all relevant and specific terms of the premarket approval.

29. Subject to additional discovery, Sientra did not comply with federal law and regulations, including but not limited to the following:

a. Requirements for contractor selection;

b. The FDA's Quality System Regulation, or QSR requirements;

c. The FDA's cGMP [current Good Manufacturing Practices] audits;

d. 21 CFR §§ 803, 808, 814, and 820;

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[3] https://www.sec.gov/Archives/edgar/data/1551693/000104746914007752/a2221455zs-1.htm

[4] https://www.sec.gov/litigation/admin/2018/33-10555.pdf

e. Other applicable sections of the Code of Federal Regulations;

f. Other applicable manufacturing standards;

g. Applicable testing and/ or quality control provisions;

h. Post-approval study requirements;

i. Post-approval reporting requirements;

j. Adverse event reporting.

30. Subject to additional discovery, Sientra did not comply with parallel State requirements, including but not limited to the Tennessee Product Liability Act and the prohibition on the sale of adulterated devices, as discussed in more detail, below.

C. Silimed and Sientra, 2007-2015

31. Silimed, as the manufacturer of the breast implants at issue in this matter, is headquartered and operates in Brazil, South America.

32. Upon information and belief, Sientra acquired Silimed's U.S. subsidiary in early 2007. In April of 2007, Silimed and Sientra entered into an Amended and Restated Exclusivity Agreement through which Sientra was granted the exclusive right to distribute Silimed's breast implants, manufactured in Brazil, in the United States and Canada for a period of ten (10) years. In return, Sientra assumed the obligation of obtaining necessary regulatory approvals for this distribution and sale, including premarket approval (PMA) from the U.S. Food and Drug Administration, incorporating information provided by Silimed.

33. Upon information and belief, confidential and proprietary information provided by Silimed to Sientra in furtherance of the premarket approval application included, but was not limited to, product manufacturing specifications, reports of risk studies, validation reports,

quality control inspections and specifications criteria, manufacturing process parameters, and manufacturing, quality control and inspection instructions.

34. Upon information and belief, Sientra was also granted access to Silimed facilities for inspections, only to the extent necessary, and for the sole purpose of, "assessing Silimed's compliance with the quality control and product warranty obligations under the agreement."[5] At a minimum, Silimed's manufacturing and business practices, including the lack of sufficient testing, audit and/or quality control measures, were made known to Sientra, or would have been fully discoverable in the exercise of due diligence and reasonable care.

35. Sientra and Silimed, after entering into this Exclusivity Agreement in April 2007, thereafter worked together, and also at cross-purposes, as documented more fully in extensive litigation between the two.[6]

36. Sientra had a duty to obtain and review all quality and quality control data and information related to Silimed's operations, including but not limited to, upon information and belief, a duty to investigate the circumstances outlined in previous warning letters from the FDA to Silimed, and/or Forms FDA-483. This duty existed prior to entering into the Amended and Restated Exclusivity Agreement, and continued after the execution of that agreement.

37. Sientra's quality department had on ongoing obligation – including but not limited to those established by contract, by the terms of the PMA, per cGMP, and pursuant to parallel State obligations - to perform periodic audits at Silimed to ensure conformity with the specifications, policies and procedures, as well as testing and quality control measures.

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[5] See Silimed v Sientra, US District Court, Southern District of New York, Civil Action No. 16-cv-8624, Complaint filed 11/6/16 at para. 40, pg. 13, referencing Section 5.3 of the Agreement between the two.

[6] In addition to other litigation, Silimed claims that Sientra first expressed interest in purchasing Silimed Brazil as early as 2005, and continued to pursue this acquisition objective throughout the parties relationship. However, Silimed refused to sell. (Id). The Complaint referenced in the previous note alleges that with Silimed's continued refusal to sell, Sientra "embarked on a scheme to misappropriate Similed's Manufacturer IP [intellectual property] and Confidential Information." (Id. At para. 46, pg. 15-16).

38. In Sientra's 2014 10-K report, the relationship between Sientra and Silimed was described, in pertinent part[7], as follows:

> "All of our products are listed under our FDA Medical Device Establishment Registration where it indicates ***we are the specification developer of our products and we are the owner of our products' FDA approvals and clearances. This means that we are primarily responsible for the manufacturing and quality assurance of our products.*** However, we do not manufacture our products ourselves. Instead, we rely on Silimed, as our contract manufacturer, to manufacture and package our silicone gel breast implants, tissue expanders and other products to our specifications…***When we receive products from Silimed, we inspect the products prior to shipping them to our customers.***
>
> We and Silimed are subject to the FDA's Quality System Regulation or QSR, reporting requirements and cGMP [current Good Manufacturing Practices] audits by the FDA. ***Under the QSR and cGMP requirements, manufacturers, including third party manufacturers, must follow stringent design, testing, production, control, supplier and contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process***….
>
> ***At present, all of our products including our silicone gel breast implants and breast tissue expanders, are manufactured by Silimed***…
>
> **There are inherent risks in contracting with manufacturers located outside of the United States such as in Brazil."**

(Emphasis added).

39. In Sientra's first quarter report for 2015, it stated:

> "**Mistakes and mishandling are not uncommon** and can affect production and supply. Some of these risks include:
>
> **Failure of our manufacturer to follow Good Manufacturing practices, or cGMP**, requirements or mishandling of our products . . .
>
> Delays in analytical results or failure of analytic techniques that we depend on for quality control . . .

[7] https://www.sec.gov/Archives/edgar/data/1551693/000104746915002407/a2223674z10-k.htm

Issues with facilities and equipment . . .; and

Latent defects that may become apparent after products have been released . . . ."

(Emphasis added).

40. The statements listed above and throughout this Complaint evidence actual knowledge of quality control risks associated with the manufacturing facility in Brazil, in violation of acceptable and required contractor selection practices and other applicable State and Federal requirements, including general requirements and also requirements specific to this PMA.

41. At all times material herein, Sientra knew of, or recklessly disregarded information about, GMP non-compliant conditions at the Silimed manufacturing plant.

42. Silimed received multiple warning letters after FDA inspections documented "serious violations" of applicable federal regulations, including prior to the use of the Sientra implants for Mrs. Hart's reconstruction. Based upon those letters and accompanying Forms FDA-483, Sientra had actual knowledge of quality control and noncompliance issues.

43. Between 2012 and 2016, Silimed was sued in Brazil at least nine (9) times over ruptures/ failures in breast implants, evidencing poor quality and quality control. Between 2012 and 2015, Italian authorities documented at least 24 Silimed-related incidents.[8]

44. At all times material herein, Sientra knew of, or recklessly disregarded information about, poor quality and quality control issues at the Silimed manufacturing plant.

[8] *See* Flynn v. Sientra, U.S. District Court, Central District of California, No. 2:15-cv-07548-SJO-RAO, Consolidated Amended Complaint for Violation of the Federal Securities Law, at pg. 12, para. 50.

45. As of March 2015 when the 2014 Annual Report was published, Sientra had incurred significant net operating losses that were anticipated to continue in the short term. According to some analysts, Sientra was not estimated to reach overall profitability until the first quarter of 2016.

46. Upon information and belief, the FDA received at least one anonymous report regarding foreign particle contamination of breast implants manufactured at the Silimed facility in Brazil.

47. Upon information and belief, in the Spring of 2015, the German health regulatory agency received a report of contamination of Silimed manufactured breast implants which referenced various particulates, including silver. Follow up inspection of additional samples, analyzed in Brazil and again in Munich, confirmed particle contamination on the surface of all samples, as reflected in a report completed July 28, 2015.

48. Upon information and belief, Silimed's own internal investigation confirmed these findings. No later than September 4, 2015, Silimed documented the presence of particle contamination of breast implants sold in the United States by Sientra.

49. Upon information and belief, Sientra's Quality Assurance team, which was responsible for receiving and reviewing complaints from US doctors and patients, received "complaints relating to the poor quality control processes at the Silimed plant in Brazil," but no corrective measures were taken and no problems were reported to the FDA.

D. Sientra and Silimed– September 2015 and forward

50. In September 2015, Sientra carried out a follow-on offering of its common stock, with the initial Form S-1 being filed with the Securities and Exchange Commission on September 3, 2015, and the offering closing on September 23, 2015.

51. On or before September 20, 2015, Sientra's then CEO was informed that the CE Certificate (European authorization) for Silimed's manufacture of breast implants had been suspended after an audit of the facility documented widespread contamination. However, the CEO of Sientra fraudulently concealed this information until the stock offering closed.

52. On September 23, 2015, the stock offering closed after selling three million shares for net proceeds of $61,397,000.

53. On or about September 24, 2015, it was announced in the media that the United Kingdom's Medicines and Healthcare Products Regulatory Agency ("MHRA") had suspended sales of Silimed products after an audit/inspection of Silimed's manufacturing processes revealed contamination in Silimed's Rio de Janeiro manufacturing plant and an inability to resolve the issue of particulate contamination. Anvisa, Brazil's health regulatory agency, suspended manufacturing authorization at Silimed on approximately September 25, 2015, and shipment of all products manufactured there. In the US, Sientra voluntarily agreed to cease sale of implants until March 1, 2016.

54. Upon information and belief, the textured breast implants produced at the Brazilian manufacturing facility were contaminated and therefore adulterated within the meaning of both State and Federal laws, including those implanted into Plaintiff Kelly Hart.

55. Also on September 24, 2015, Sientra sent a letter to plastic surgeon customers disclosing the loss of the European manufacturing certificate, and filed a Form 8-K report of same.

56. On approximately October 22, 2015, a fire occurred at Silimed's Brazilian manufacturing facility in the building that was the primary location of the manufacture of breast implants. The fire caused extensive but unknown damage, potentially destruction of evidence/ records, and required manufacturing to be shifted to another building.

57. As a result of Sientra's fraudulent concealment of relevant information regarding contamination at the manufacturing facility, Sientra stock initially dropped more than 52%, with additional drops as more information came to light regarding the extent of the contamination. Shareholders filed suit against Sientra, Hani Zeini (as the President, Director, and CEO), and Matthew Pigeon (the Treasurer and CFO).[9] Based on publicly available information, the shareholder class action was ultimately settled for an amount in excess of ten million dollars ($10,000,000), with insurance policies as well as the company itself contributing.

58. The Securities and Exchange Commission also instituted regulatory action for fraudulent conduct.[10] Allegations in that matter include statements that even after the stock offering closed, Zeini continued to lie about the matter, *and attempted to destroy records which implicated him in earlier knowledge*.[11] The former CEO, who had been forced to step down in November 2015, was ordered to pay a civil penalty of $160,000, consented to entry of judgment permanently enjoining him from violating Section 17(a) of the Securities Act and Section 10(b)

[9] Flynn et al v. Sientra et al, US District Court, Central District of California, Case 2:15-cv-07548 filed 9/25/15.
[10] In re: Seintra, US Securities and Exchange Commission, administrative file No. 3-18795; SEC v. Zeini, No. 18-cv-08103 (C.D. Cal).
[11] SEC Litigation Release No. 24567, August 16, 2019.

of the Exchange Act, and imposed a bar preventing him from serving as an officer or director for five (5) years. (*Id).*

E. Federal Laws and Regulations

59. Section 520(f) of the Food, Drug and Cosmetic Act gives the FDA authority to create regulations requiring that the methods, facilities, and controls used for the manufacture, packing, storage, and installation of medical devices conform to good manufacturing practices.

60. Manufacturers of Class III medical devices are subject to an ongoing obligation to comply with Medical Device Reporting (MDR) requirements.

61. Applicable Federal regulations include, but are not limited to the following:

21 CFR 803.10	*Regarding Adverse Event Reporting*
21 CFR 803.17	*MDR Reporting*
21 CFR 803.18	*MDR Reporting*
21 CFR 803.50(a)	*Regarding Adverse Event Reporting*
21 CFR 808.1(d)(2) and (6)(ii)	*When State laws are not preempted*
21 CFR 814.39	*Submission of a PMA Supplement for material changes*
21 CFR 814.82	*Regarding Post Approval requirements*
21 CFR 814.84	*Requiring Post Approval reporting*
21 CFR 820.20	*Required Establishment of Quality Policy*
21 CFR 820.30	*Design Controls*
21 CFR 820.5	*Quality System*
21 CFR 820.70	*Production and Process Controls*
21 CFR 820.75	*Process validation*

21 CFR 820.86	*Acceptance Status- conformance or nonconformance*
21 CFR 820.90	*Nonconforming Product*
21 CFR 820.100	*Corrective and Preventive Actions*
21 CFR 820.140	*Handling*
21 CFR 820.198	*Manufacturer Complaint Files*

62. Upon information and belief, Sientra violated all of the foregoing.

63. Upon information and belief, Sientra also violated standards promulgated by the International Organization for Standardization (ISO), including but not limited to ISO 10993-Part 1 (Biological evaluation of medical devices, evaluation and testing).

64. In approximately 1997, the FDA promulgated the Quality System Regulations, or QSRs. Under the QSRs, medical device manufacturers were required to "establish and maintain a quality system that is appropriate for the specific medical devices designed or manufactured, and that meets the requirements of" the QSRs. 21 CFR § 820.5. This system is known as the Quality Management System.

65. Failure to comply with the QSRs renders a device "adulterated."

66. Devices not in conformity with performance standards are deemed "adulterated." 21 U.S.C. §351 (e).

67. The contamination of the Sientra implants, including but not limited to contamination with surface particulates, also renders the devices adulterated.

68. Further, 21 U.S.C. Sec. 351(h) defines an adulterated device, in part, as resulting when "the methods used in, or the facilities or controls used for, its manufacture, packing, storage or installation are not in conformity with applicable requirements."

69. Adulterated devices are not subject to preemption. 21 CFR 808.1(d)(2) and (6)(ii).

F. State Laws and regulations

70. T.C.A. 53-1-103 prohibits the sale or delivery of any medical device that is adulterated or misbranded. T.C.A. 53-10-106(a)(2) further provides that:

> "Any drug or device that is deemed misbranded or adulterated by federal law is deemed misbranded or adulterated within the purview of this section."

71. Plaintiff further relies on the Tennessee Product Liability Act, found at T.C.A. 29-28-101 et seq.

72. Plaintiff relies on warranties acknowledged under Tennessee law, both express and implied, including but not limited to those codified at T.C.A. §§ 47-2-313, 47-2-314, and 47-2-315, including the warranty of fitness for a particular purpose.

G. BIA-ALCL and contaminated/ adulterated textured implants

73. The contaminants documented during the September 2015 inspection and audit were identified as man-made mineral fibers such as silicum carbide, glass (identified as glass wool and rock wool), and iron particles.

74. The contaminants were further identified as particulates and fibers commonly used as building insulation materials. These materials create a carcinogenic risk, even after removal of the implant, as some fibers may remain in the body.

75. Fragments and/or contaminants adhered to the surfaces of the implants due to inadequate/ improper manufacturing processes, materials, cleaning, testing and/or inspection for defects.

76. The implants were not subject to adequate quality control or validation, rendering them adulterated with foreign sharp particles, fragments, residues, and/or adulterants from the manufacturing process itself or from inadequate cleaning, testing or inspection, and became

embedded into the plaintiff's breast tissue when implanted causing or contributing to BIA-ALCL.

77. According to the MHRA investigative report[12] referenced above, the foreign objects That adulterated or contaminated the silicone breast implants, such as those implanted into Plaintiff, induce inflammation which can lead to the formation of fibrosis and granuloma formation.

78. The mechanism of toxicity and induced disease resulting from these contaminated particles and fibers is similar to the body's response to other foreign objects, including but not limited to inflammation and/or encapsulation.

79. When an implant is negligently manufactured, overly textured, rough implant shells are produced with foreign and adulterated silicone particles, fragments, implant materials and residues on the implant surface that are recognized as a foreign body that triggers T-cell lymphoma and over time, BIA-ALCL.[13]

80. It is well established in the medical community that implant debris cause local inflammation, worsening over time. Furthermore, there are individuals who are more susceptible to BIA- ALCL or hypersensitivity-type adaptive immune responses, and will be more vulnerable to implant debris than the general population.[14]

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[12] https://rivm.openrepository.com/bitstream/handle/10029/620771/2015-0202.pdf?sequence=3

[13] *See also* "Silicone particle induced inflammation is the primary cause of BIA-ALCL." Dennis Hammond, MD, *Presentation at 1st World Consensus Conference on BIA-ALCL* (Rome Italy, Oct. 5, 2019)(emphasis added), https://youtu.be/YxPFayQsjUo?t=24447 (slide presented during his presentation, "*The Micro-particulate theory and the role of innate immunity*" as part of a scientific panel addressing the etiopathogenesis of BIA-ALCL). *See also* Backovic, et al., *Silicone mammary implants – Can we turn back the time*? Experimental Gerontology Volume 42, Issue 8, August 2007 ("silicone degradation products promote protein denaturation and activate cells of both the innate and adaptive immune system, thus perpetuating a chronic pro-inflammatory response of the local tissue."). https://www.sciencedirect.com/science/article/pii/S0531556507000824?via%3Dihub

[14] Hallab, Smerko, Hammond, *The Inflammatory Effects of Breast Implant Shedding: Comparison With Orthopedic Implants,* Aesthetic Surgery Journal Vol 39 (S1) S36-S48 (Jan. 30, 2019), available at https://www.semanticscholar.org/paper/The-Inflammatory-Effects-of-Breast-Implant-With-Hallab-Samelko/7635841c2edd2b45000c04641befa345a46028e7

81. In addition, if bacteria attach to the surface of an implant, including a textured surface and/or contaminants, and create a biofilm, the biofilm over time becomes almost impossible to remove. This bacterial biofilm can additionally cause, contribute to, or exacerbate chronic inflammation and known sequelae, including infection, capsular contracture, double capsule and breast implant-associated ALCL (BIA-ALCL). [15]

82. The link between bacterial biofilm and BIA-ALCL is well documented in scientific literature.[16] Further, according to Sientra's own Medical Affairs department, a "wealth of evidence has demonstrated a link between chronic inflammation . . . in the pathogenesis of BIA-ALCL."[17]

83. The textured Sientra breast implants utilized for Mrs. Hart's reconstruction, after prophylactic risk-reducing bilateral mastectomies to prevent breast cancer, directly and proximately caused her breast implant associated anaplastic large cell lymphoma (BIA-ALCL), injuries, damages and losses. In the alternative, the implants were a substantial factor in causing the BIA-ALCL, which she would not have been diagnosed with but-for their placement. The Sientra implants were likewise a direct and proximate cause of, or a substantial factor in causing, Plaintiff Seth Hart's injuries, losses and damages.

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[15] https://www.ncbi.nlm.nih.gov/pubmed/23924649 Deva, A.K. Adams, W.P., Jr. & Vickery, K. (2013). *The role of bacterial biofilm in device-associated infection.* Plast Reconstr Surg, 132(5), 1319-1328.

[16] See Ye *et al*, *Anaplastic large cell lymphoma (ALCL) and breast implants: Breaking down the evidence,* Mutation Research 762 (2014) 123–132. https://www.sciencedirect.com/science/article/pii/S138357421400043X?via%3Dihub:

[17] https://sientra.com/Content/pdfs/Sientra%2014%20Point%20Plan%20%20BIA-ALCL%20FAQ_2017.pdf

H. Injuries and Damages

84. The Plaintiffs bring this matter seeking all categories of available damages, including but not limited to those outlined in more detail below.

85. As a direct and proximate result of the causes of action alleged herein, Mrs. Hart was caused to endure physical pain and suffering, which may continue into the future, and has suffered permanent physical impairment and disfigurement. She has been caused to undergo additional medical procedures, and will require additional monitoring and treatment in the future.

86. As a further direct and proximate result of the causes of action alleged herein, Mrs. Hart has been caused to endure tremendous mental suffering, as she was faced with contracting breast cancer from a procedure she elected to have performed for the sole and explicit purpose of *preventing* the possibility of breast cancer. It is anticipated that this mental suffering will continue throughout her life, as she worries about a recurrence, her health and safety, and the stability, love and obligations of her family. She has suffered and will likely continue to suffer emotional distress, and also a loss of enjoyment of life.

87. As a further direct and proximate result of the causes of action alleged herein, Plaintiff Seth Hart has suffered and will continue to suffer the loss of his wife's love, companionship, consortium, and services.

88. As a further direct and proximate result of the causes of action alleged herein, Plaintiffs have suffered economic losses, including but not limited to incurred medical expenses, likely future medical expenses, Mrs. Hart's loss of earning capacity, and other financial losses associated with increased medical insurance premiums and increased life insurance premiums, or the lack of availability of such policies.

Causes of Action[18]

89. Plaintiffs rely on and incorporate by reference all facts and allegations contained herein, regardless of the section or paragraph in which they appear. In addition, it is believed that additional facts and information that are uniquely known to, and under the control of, the Defendant may be developed in discovery in further support of these claims.

I. Negligence

90. Tennessee State law includes claims parallel to federal requirements.

91. Tennessee law does not impose duties materially different from the federal ones described herein, and there is no preemption.

92. Defendant had a duty to exercise reasonable care in the design, manufacture, marketing, selling, and distributing of the Sientra devices, including, but not limited to, ensuring that the devices did not pose risks and dangers of adverse events to those implanted with the devices.

93. Defendant breached its duty of reasonable care by designing, manufacturing, marketing, selling, distributing, and failing to adequately warn patients and physicians of the risks and dangers associated with the use of adulterated textured silicone breast implants and the risk of developing BIA-ALCL as a result of the use of these products.

[18] These causes of action are being raised in good faith after a full review *of Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), subsequent case law, applicable statutes, and other authoritative and advisory resources regarding the issue of preemption, either (1) to extend, modify or reverse existing precedent, or (2) for review of an issue of first impression. More particularly, Plaintiffs assert, cumulatively and/or alternatively, that parallel state law claims exist which preclude this action from being subject to preemption; that preemption should not apply in a circumstance of a manufacturing defect and/or adulterated product not manufactured in compliance with FDA regulations and standards; and/or that the protections of premarket approval and preemption should not be granted where a defendant failed to comply with the conditions of the approval in aspects including but not limited to contractor selection, manufacturing standards, QSR requirements, cGMP audits, other applicable manufacturing standards, other applicable quality and safety standards, post-marketing studies, PAS reporting, and adverse event reporting, and further where the defendant has been accused of fraudulent conduct by both the Securities and Exchange and its own shareholders, and has also been engaged in litigation based on allegations of improper conduct with the manufacturer at issue here.

94. Defendant had a duty to exercise reasonable care in the selection of a manufacturer.

95. Defendant breached its duty of reasonable care in choosing Silimed to manufacture the textured breast implants when it had actual knowledge of "inherent risks in contracting with manufacturers located outside of the United States, such as in Brazil," and either had actual knowledge about, or recklessly disregarded information pertaining to, prior quality problems at the Silimed facility and/or noncompliance with all applicable regulations, standards, obligations and laws.

96. Defendant Sientra, through its reliance on Silimed's Brazilian manufacturing facility as its sole manufacturer, negligently manufactured textured breast implants using a manufacturing process that adulterated products with manufacturing defects caused by Silimed's violation of FDA and PMA standards, which also supports parallel state law claims.

97. Defendant had a duty to exercise reasonable care to comply with the terms of the FDA PMA approval, both specific to this device and in general, and also the approval letter.

98. Defendant breached its duty of reasonable care by failing to comply with the terms of the approval, including but not limited to terms regarding design, contractor selection, manufacturing, post-approval studies, quality control, and discovering and reporting adverse events after the premarket approval.

99. Defendant had a duty to exercise reasonable care to comply with all federal and state regulations and laws with regard to the design, manufacture, testing, inspection, marketing, selling, and distributing of textured breast implants, and also the development and dissemination of warning and adverse event reporting regarding them.

100. Defendant breached its duty of reasonable care by failing to comply with all federal

and state regulations and laws, including but not limited to, those identified in paragraphs 59, 60, 61, 63, 64, 70, 71 and 72.

101. Defendant Sientra was negligent and/or negligent per se in failing to comply with all federal and state regulations and laws, including but not limited to, those identified in paragraphs 59, 60, 61, 63, 64, 70, 71 and 72.

102. In addition to the foregoing and as stated otherwise herein, Defendant Sientra was Negligent and/or negligent per se, as evidenced by – but not limited to – the following:

a. Contracting to have the breast implants manufactured in Brazil;

b. Failing to exercise due care in choosing Silimed as the manufacturer;

c. Failing to manufacture the implants so as to avoid contamination and/or adulteration;

d. Manufacturing implants that differ from the specifications of the PMA;

e. Failing to disclose the additional risks associated with contaminated, adulterated, and/or textured implants;

f. Failing to establish and/or enforce a reasonable quality control program;

g. Failing to sufficiently test samples and manufacturing processes;

h. Failing to reasonably inspect product samples and manufacturing processes;

i. Failing to adequately train and/or supervise employees;

j. In negligently and carelessly marketing and promoting the use of the textured implants to physicians who had not received sufficient training regarding inspection for particles, so as to avoid an unreasonable risk to women;

k. Failing to reasonably conduct post-market surveillance;

l. Failing to report to MAUDE (Manufacturer and User Facility Device Experience), a tracking database maintained online;

m. Failing to identify the risk of BIA-ALCL in a timely manner;

n. Failing to warn regarding the risk of BIA-ALCL;

o. Failing to exercise reasonable care in the contractor selection, manufacturing, inspection, testing, and quality control processes;

p. Failing to report quality control issues;

q. Failing to investigate information regarding quality control issues at the manufacturing plant in Brazil;

r. Failing to follow up on information regarding quality control issues at the manufacturing plant in Brazil;

s. Failing to timely discover and/or disclose the product contamination and/or adulteration; and

t. Failing to exercise due and reasonable care at all times material herein.

103. In addition, Defendant Sientra violated Tennessee tort law by failing to comply with the reporting duties under federal law. These reporting requirements include, but are not limited to, any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety and effectiveness or performance of a medical device after said device is released for distribution.

104. Despite the fact that Defendant knew or should have known of inherent, adverse and/or increased risks, Defendant continued to manufacture, market, sell, and distribute the Sientra devices manufactured in Brazil by Silimed.

105. Defendant Sientra knew that particles or contaminants on the surface of its textured silicone breast implants manufactured by Silimed should not be implanted into patients and that surgeons should not use any product with particulate contamination. Sientra further knew that PMA and FDA requirements, including but not limited to the prohibition of "adulterated" products and requirements to remove manufacturing material would be violated where foreign particles were left on the implant surface.

106. As a direct and proximate cause of Defendant's negligence, Plaintiffs have suffered and will continue to suffer injuries and significant damages, including but not limited to those described hereinabove.

II. Strict Liability – Manufacturing Defects

107. Defendant Sientra developed, manufactured, and sold Mrs. Hart's textured breast implants used in her reconstruction after risk-reducing mastectomies.

108. Defendant Sientra, in the Form 10-K filed with the Securities and Exchange Commission on March 18, 2015[19], admitted that it was the "specification developer" of their products and stated that they were primarily responsible for the manufacturing and quality assurance of their products.

109. The breast implants were defective and unreasonably dangerous pursuant to the laws of the State of Tennessee, and as specifically defined in the Tennessee Product Liability Act, T.C.A. §29-28-101 et seq.

110. The breast implants were adulterated, as defined in T.C.A. §53-10-106(a)(2).

111. Mrs. Hart's breast implants were defective, unreasonably dangerous, and unsafe

[19] https://www.sec.gov/Archives/edgar/data/1551693/000104746915002407/a2223674z10-k.htm

when they left Defendant Sientra's control. Sientra knew or should have known this when it manufactured, marketed, and sold the implants.

112. Sientra was responsible for its products manufactured by Silimed and knew or should have known that said products were defective and in an unreasonably dangerous condition when put to a reasonably anticipated use.

113. Defendant Sientra is strictly liable for injuries and losses caused by the unreasonably dangerous, defective, and unsafe implants.

114. The adulterated/contaminated breast implants were used in such a manner that when implanted into Plaintiff Kelly Hart, they caused her to develop cancer associated with said implants (BIA-ALCL).

III. Strict liability – Failure to Warn

115. The Sientra devices placed into the stream of commerce by Defendant Sientra were defective in that they were not accompanied by an adequate warning, as Defendant knew or should have known that the Sientra devices were contaminated, adulterated, and/or carried an increased risk by virtue of being manufactured at a facility in Brazil, and/or as a result of the textured surface, and were therefore likely to cause severe pain, suffering, debilitating physical conditions, and permanent injury. Defendant failed to provide adequate warnings of these risks to Plaintiff and to other patients, physicians, and consumers of the Sientra devices.

116. Defendant Sientra knew or should have known of the increased risk of cancer associated with their textured implants manufactured in Brazil.

117. Defendant Sientra failed to warn the Plaintiff, her physician, and/or other relevant

stakeholders regarding the increased risk of cancer associated with their textured implants that were manufactured in Brazil.

118. Defendant Sientra knew or should have known of the increased risk of cancer associated with contaminated and/or adulterated implants.

119. Defendant Sientra failed to warn the Plaintiff, her physician, and/or other relevant stakeholders regarding the increased risk of cancer associated with their contaminated and/or adulterated implants.

120. Defendant Sientra specifically failed to inform physicians, patients, and/or purchasers of significant risks of their products, including but not limited to the following:

a. That the product was manufactured by a facility in Brazil;

b. That there were inherent risks in contracting with a manufacturer outside of the United States, including Brazil;

c. That the reliance on Silimed involved a risk that the product might not be manufactured in accordance with agreed upon specifications, which could negatively affect the safety or efficacy of the product;

d. That the reliance on Silimed involved a risk that the product might not be manufactured in compliance with regulatory requirements, which could negatively affect the safety or efficacy of the product;

e. That a risk existed that the manufacturing facility might not be able to maintain compliance with regulatory requirements, which could negatively affect the safety or efficacy of the product;

f. That mistakes and mishandling were not uncommon, and could affect the production and supply;

g. That the manufacturer could fail to follow current Good Manufacturing Processes (cGMP), despite being required to do so;

h. That there could be delays in analytical results or failure of analytic techniques that were relied on for quality control;

i. That the manufacturing facility in Brazil had been subject to other quality failures;

j. That textured implants carry an increased risk of cancer;

k. That contaminated implants carry an increased risk of cancer;

l. That adulterated implants carry an increased risk of cancer; and/or

m. That significant risks were associated with textured, contaminated, and/or adulterated implants manufactured in a facility in Brazil that might not comply with applicable regulations and safety controls, and which had a history of previous quality failures, all of which Sientra knew or should have known when choosing to have the implants manufactured there.

121. Defendant Sientra is strictly liable for their failure to warn under relevant Federal and parallel State laws.

IV. Breach of Express and Implied Warranties

122. Defendant designed, manufactured, tested, marketed, and distributed into the stream of commerce the Sientra implant devices, including the ones implanted into Plaintiff.

123. The textured breast implants utilized for Plaintiff Kelly Hart were neither merchantable, nor fit for the particular purpose for which they were produced and sold, thereby breaching warranties, both express and implied, including but not limited to those stated in

T.C.A. §§ 47-2-313, 47-2-314, and 47-2-315, including the warranty of fitness for a particular purpose.

124. Upon information and belief, Defendant expressly warranted to Plaintiff Kelly Hart and her physician, Dr. Jay Lucas, by means including but not limited to communication with or through their authorized agents or sales representatives, in publications, package inserts, the internet, and other communications intended for physicians, medical patients, and the general public that Sientra devices were safe, fit, and proper for their intended use.

125. Upon information and belief, in his decision to implant the Sientra devices into Plaintiff Kelly Hart, Dr. Lucas relied on the skill, judgement, representations, and warranties of Defendant.

126. The express warranties Defendant made were false in that the Sientra devices were not safe, fit, or proper for their intended use.

127. The Sientra devices did not conform to the Defendant' express and implied warranties and representations because the device was not manufactured in compliance with the terms and parameters of the FDA approval, thereby causing injury, pain and suffering, and the need for additional surgery to remove the devices due to the development of BIA-ALCL as a result of the use of said devices, with the attendant risks of complications and death from such further surgery.

128. As a direct and proximate cause of Defendant's breach of their express and implied warranties regarding the safety and effectiveness of the Sientra devices, Plaintiffs have suffered and will suffer injuries and significant damages, including, but not limited to physical injury, impairment and/or disfigurement, medical complications, pain and suffering, mental and emotional anguish, fear of future injuries, loss of enjoyment of life, significant medical expenses,

future medical expenses, loss of consortium, and other specific and general damages as described in more detail above.

129. Defendant knew the use for which the Sientra devices were intended and impliedly warranted the devices to be of merchantable quality and safe for such use.

130. Plaintiffs and Dr. Lucas reasonably relied upon the skill and judgment of Defendant as to whether the Sientra devices were of merchantable quality and safe for the intended use.

131. Contrary to Defendant's warranties, the Sientra devices were not of merchantable quality or safe for the intended use because they were unreasonably dangerous as described above.

132. As a direct and proximate cause of Defendant' breach of the implied warranty of merchantability regarding the safety and effectiveness of the Sientra device, Plaintiffs have suffered and will suffer injuries and significant damages, including, but not limited to physical injury, impairment and/or disfigurement, medical complications, pain and suffering, mental and emotional anguish, fear of future injuries, loss of enjoyment of life, significant medical expenses, future medical expenses, loss of consortium, and other specific and general damages, as more fully described above.

133. As a direct and proximate cause of Defendant' wrongful conduct, Plaintiff has suffered and will suffer injuries and significant damages, including, but not limited to physical injury, medical complications, pain and suffering, mental and emotional anguish, fear of future injuries, loss of enjoyment of life, significant medical expenses, future medical expenses, and other specific and general damages.

V. Punitive Damages

134. All of the foregoing facts and violations are specifically referenced and relied upon in support of Plaintiffs' claim for punitive damages. The acts and omissions of Sientra, and previously stated and alleged, were reckless, intentional, and /or fraudulent so as to subject the Defendant to punitive damages.

135. Sientra's choice of Silimed to manufacture the breast implants in Brazil was reckless, intentional, and /or fraudulent, where it knew or should have known of quality control issues and risks, including but not limited to prior FDA warnings for noncompliance, prior quality control issues, prior product failures of devices manufactured there, and what the company itself described as "inherent risks" of manufacturing in Brazil that could result in violation of the terms of the approval, along with applicable laws, regulations, current Good Manufacturing Practices, QSRs, and other relevant standards.

136. The failure to comply with the terms of the PMA was reckless, intentional, and /or fraudulent.

137. The failure to comply with all FDA requirements was reckless, intentional, and /or fraudulent.

138. The failure to comply with current Good Manufacturing Practices was reckless, intentional, and /or fraudulent.

139. The failure to comply with QSRs was reckless, intentional, and /or fraudulent.

140. The failure to comply with all other applicable manufacturing standards was reckless, intentional, and /or fraudulent.

141. Allowing adulterated products to be manufactured, and/or packaged, sold and delivered, was reckless, intentional, and /or fraudulent.

142. The lack of appropriate quality control processes was reckless, intentional, and /or fraudulent.

143. Failing to warn the Plaintiffs and Mrs. Hart's physicians of the risks associated with a product manufactured in Brazil reckless, intentional, and /or fraudulent.

144. Failing to warn the Plaintiffs and physicians of the full scope of risks associated with these textured implants manufactured in Brazil, and more fully addressed above, was reckless, intentional, and /or fraudulent.

145. The conduct of Defendant Sientra, as described herein, but also as documented in other litigation, including but not limited to litigation with its own shareholders, with the Securities and Exchange Commission, and with Silimed, evidences a reckless disregard for the public's safety and welfare, and also for the safety and welfare of Mrs. Hart, in particular. This conduct further evidences a prioritization of profit over quality and safety that is offensive and which should be both punished and deterred.

PRAYER FOR RELIEF

Wherefore, Plaintiffs demand judgment against Defendant Sientra for all such compensatory, statutory, and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees, and all such other, further or general relief which this Court may deem proper.

Respectfully submitted, on this the 23rd day of September, 2020.

/Leslie A. Muse_____
Leslie A. Muse (BPR# 018150)
Butler, Vines & Babb, PLLC
Attorneys for Plaintiffs
2701 Kingston Pike
Knoxville, TN 37919
(865) 637-3531